UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/312,485	05/17/99	DEBREGEAS	P 065691/0163

HM22/0921

FOLEY AND LARDNER
WASHINGTON HARBOUR
3000 K STREET NW STE 500
P O BOX 25696
WASHINGTON DC 20007-8696

EXAMINER	
SHARAREH,S	
ART UNIT	PAPER NUMBER
1619	12

DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Advisory Action	Application No.	Applicant(s)	
	09/312,485	DEBREGEAS ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1619	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 August 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-21*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 2. NOTE: first, the scope of the claim has been modified to limit the coating to only two element; the plant substance and a pharmaceutically acceptable excipient. second, the amendment raises new 112 2nd issues. for example, the dependent claims 4, 5, 6 further limits the coating to contain additional elments such as a binder or an outer layer showing delayed release properties, accordingly, sething forth the issue of improp r dependency wherein dependent claims are broader than their base claims. finally, the amendent renders the recitation of claim 4 indefininte, because it is not clear whether a the pharamceutically acceptable excipient of claim 1 is a binder, or the binder is an additional component. thus, the amendment as a whole requires further search and consideration.

Continuation of 3. Applicant's reply has overcome the following rejection(s): rejection of claims 1,5,9,11-12 under 35 USC § 102 (b) over WO 97/04861 and the rejection of claims 1-2, 4-9 over Jacob et al US 5,733,551.

Continuation of 5. does NOT place the application in condition for allowance because: first, Applicant's arguments with respect to rejection of claims 1-2, 4-5, 9-13 16-20 under 35 USC 102 (b) as being anticipated by Cingotti US 5,427,800 has been fully considered but are not found persuasive. Applicant argues that Cingotti does not teach the instant diameters of neutral core. In repsonse Examiner states that during patent examination, the pending claims are given their broadest reasonable interpretation(MPEP 2111). Here, there is no indication in the claims what encompasses a pharmaceutically acceptable excipient, accordingly, Examiner views such recitation given its broadest reasonable interepreation. Cingoti discloses two final granules, the coated silica, and the coated sorbitol neubulized microgranules (example 1). specifically, Cingoti discloses that once the coated granules are gauged, these granules are absorbed ON and IN nebulized porous excipient microgranules that are standard in pharmaceutical industry (col2, lines 58-60). Then Cingoti discloses that the sorbitol nebulized microgranules are coated with the coated silica granules to form the final microgranules having dimenstions of 0.1 to 1 millimeter (col 4, lines 1-16, col 3, lines 1-5). Cingotti specifically says that the sorbital microgranules (analogous component as instant neutral core) have particle size of 210-800 µm (col 4, lines 5-9). accordingly, Cingoti discloses the claimed ranges. furthermore, applicant's assertion that the instant coating contains only two component is not persuasive because the coated granules of Cingotti only contain a silica powder and a plant substance and said coated granules is constured as pharmacetically acceptable excipient having a plant substance. Therefore, Cingotti meets the limitations of the instant claims.

Applicant's arguments with respect to the rejection of claims 3, 6-8, 14, 15, 21 under 35 USC § over CIngott, Menzi, and Breitenbach has been fully considered but not found persuasive for the reasonas of record. More specifically, all elements of the claimed invention is taught by the cited prior art. furthermore applicant has not provided any evidence indicating the criticality of the claimed concentrations of diluents and components of core material and their unexpected results. Thus, the claims stand rejected as of record

Continuation of 10. Other: Applicants arguments with respect to finality of the previous Office Action, filed on May 31, 2001 have been fully considered but are not found persuasive. First, the scope of the claim 1 was modified in the amendment filed on March 2, 2001 as to the recitation of the modifier "each" in the originally filed claim 1. The reciation of "each" in the claim 1 as originally filed encompass granules having plant substance, each plant substance are viewed to be characterized in having neutral core having a particle size.....etc. (see original claim 1). however, the amendement of March 2, 2001 changed the scope of the claim to only encompass granules comprising a neutral core and a coating wherein the coating contains a plant substance. Accordingly there had been a shift in the elemental components of the final product. Furthermore, the rationale of finality necessitating a new grounds of rejection does not need to be based on a prior art rejection, therefore, amendments in response to a 112 2nd rejection can invoke a change of scope and thus the interpretation of the claims. Finally, Applicant's belief that the amendment of March 2. 2001 to claim 1, was merely cosmetic in nature and that the questioned phraseology is common in international claims is not persuasive, because submission to USPTO requires the Applicant to conform with United States claim drafting standards and not the international standards. Applicant is informed that to bring the prosecution to as speedy conclusion as possible, the claims are fully prosecuted as presented; not as what they could have meant or should have meant. Switching from one subject matter to another in the claims presented by applicant in successive amendments tend to defeat attaining the goal of reaching a clearly defined issue and a speedy prosecution. Accordingly, the finality of the previous Office Action was proper.

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600